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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,691	11/05/2001	Mircea Alexandru Mateescu	6670/0K000US0	9775

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DARBY & DARBY P.C.  
805 Third Avenue  
New York, NY 10022

EXAMINER

MONDESI, ROBERT B

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/021,691

Applicant(s)

MATEESCU ET AL.

Examiner

Robert B Mondesi

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 24 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1. 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to cardioprotective composition, classified in Class 514, subclass 6, Class 426, subclass 656, Class 426, subclass 541, Class 530, subclass 380.
- II. Claim 15-21, drawn to method of treatment of heart oxidative stress, classified in Class 514, subclass 6.
- III. Claim 22, drawn to method of preparation of cardioprotective composition, classified in Class 514, subclass 6.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case process as claimed can be practiced with another materially different product such as glutathione.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case process as claimed can be used to make another materially different product such as cough syrup.

Group II is distinct and independent from Group III because it is directed to different statutory class of invention and, the practice of one invention will not result in

Art Unit: 1653

the practice of the other invention, i.e. treating heart oxidative stress related condition is not a process that prepares per se the composition, nor would a search have necessarily been coextensive for any one group in view of any one or two other groups.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

During a telephone conversation with Mr. Peter Ludwig on 8-04-03 a provisional election was made without traverse to prosecute the invention of Group I drawn to a Cardioprotective Composition (claims 1-14). Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-22 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

The instant application was filed November 5<sup>th</sup>, 2001. This application is a continuation of PCT/CA00/00528, filed May 5<sup>th</sup>, 2000, which in turn claims foreign priority to Canada 2,271,192, filed May 5<sup>th</sup>, 1999. A certified copy of the foreign priority document has not been submitted.

***Information Disclosure Statement***

The IDS filed 11/05/2001 has been received, entered and considered. A signed copy is attached.

***Specification***

The use of the trademark Desferal has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and the claims dependent there to which do not address the ambiguity of the phrase "and/or" are indefinite. It is not clear if the composition in claim 1 includes a functional derivative of ceruloplasmin as a substitute for ceruloplasmin or as an addition. A functional derivative of ceruloplasmin cannot be a substitute and an addition simultaneously. In its current format the claim is indicating that a functional derivative of ceruloplasmin is a substitute and an addition simultaneously.

Claim 3 is indefinite as to the recitation of "at least one lipid" (line 12) as being "free fatty acids and mixtures thereof" since mixtures is not closed by recitation of the amount and type of at least one lipid in each mixture.

In claim 4, it is stated that "at least one fatty acid consist of a mixture of saturated and unsaturated fatty acids". This statement is indefinite because it is not possible for one of any item to be a mixture. In order for a mixture to exist there must be at least two components.

Claim 7 is indefinite (line 29) as to the double recitation "in an in an".

Claim 8 is indefinite as to the recitation of "pyruvate" (line 1) as being "prodrugs of pyruvic acid and mixtures thereof" since mixtures is not closed by recitation of the amount and type of pyruvate in each mixture.

Claim 11 is indefinite as to the recitation of "at least one antioxidant" (line 13) as being "pharmaceutically acceptable salts thereof, and mixtures thereof" since mixtures

Art Unit: 1653

is not closed by recitation of the amount and type of "at least one antioxidant" in each mixture.

Claims 11,12 and 14 are Markush claims. If a singular item is selected from a Markush group, then the individual components of the group cannot appear in plural. In claim 11, at "least one antioxidant" is singular but "pharmaceutical salts" is not singular. In claim 12, "at least one antioxidant" is singular but "analogues of Vitamin E" is not singular. In claim 14 "an agent" is singular but "metal chelators, metal scavengers, proteinic metal chelators, proteinic scavengers, preserving agents, solubilizing agents, stabilizing agents, wetting agents, emulsifiers, salts, buffers and coating agents" are not singular.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Dumoulin, et al. (1996) *Arzneim. Forsch./Drug Res.*, 46, 855-861. **Claim 1** is rejected because **claim 6** is a dependent claim that further defines the limitations of **claim 1**. **Claim 6** states that ceruloplasmin or its functional derivative is purified from blood using an one-step affinity chromatography method on aminoethyl-agarose.

In Dumoulin et al, on page 856, section 2.2, titled Ceruloplasmin Purification, it is clearly stated and explained how to purify ceruloplasmin from blood, utilizing a single step affinity chromatography method on aminoethyl-agarose.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 rejected under 35 U.S.C. 103(a) as being unpatentable over Gokhale, et al. (1997) Toxicol. in Vitro 11, 753-759, in view of Atanasiu, R. et al. (1995) Can. J. Physiol. Pharmacol., 73, 1253 - 1261.

Gokale et al. teach, on page 757, lines 5 to 14, a composition comprising a therapeutically effective amount of pyruvate (10-30 mM), vitamin E (5-25 units) and lipid (0.1-0.5%, v/v of saturated and unsaturated fatty acids). **(Claims 1-14).**

Atanasiu et al., on page 857, section 3.2.1 titled Ceruloplasmin, teaches a therapeutically effective amount of ceruloplasmin (0-1  $\mu$ m). **(Claims 1-14).**

Gokale does not teach a therapeutically effective amount of ceruloplasmin but Atanasiu teaches a therapeutically effective amount of ceruloplasmin.

One of ordinary skill in the art would have combined Gokale et al. and Atanasiu et al. for the advantages of a cardioprotective therapeutically effective composition, (Atanasiu et al., page 1256, column 2, lines 19-28 and Gokhale et al., page 757, column 1, lines 5-13) that would be utilized in the reduction of cardiac cell damaging free radicals. As combined, the result is the composition of **claims 1-5, 7-13**. Thus, the claimed invention was prima facie obvious.




**Conclusion**

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 703-305-4445. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

  
RBM  
08-24-03



CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600